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Re-evaluation Decision

RVD2011-07

Copper and Zinc Naphthenate Salts

(publié aussi en français)

31 October 2011

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada 

ISSN: 1925-1017 (print)
1925-1025 (online)

Catalogue number: H113-28/2011-7E (print version)
H113-28/2011-7E-PDF (PDF version)

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Re-evaluation Decision

After a re-evaluation of the wood and material preservatives copper and zinc naphthenate salts, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing copper and zinc naphthenate salts for sale and use in Canada.

An evaluation of available scientific information found that products containing copper and zinc naphthenate salts do not present unacceptable risks to human health or the environment when used according to the revised label directions. As a condition of the continued registration of copper and zinc naphthenate salts uses, new risk-reduction measures must be included on the labels of all products. Additional data are required as a result of this re-evaluation.

The regulatory approach for the re-evaluation of copper and zinc naphthenate salts was first presented in Proposed Re-evaluation Decision PRVD2010-16, *Copper and Zinc Naphthenate Salts*, a consultation document.¹ This Re-evaluation Decision² describes this stage of PMRA's regulatory process for the re-evaluation of copper and zinc naphthenate salts as well as summarizes the Agency's decision and the reasons for it. Following the publication of the PRVD2010-16, the PMRA determined that a reduction of the maximum guarantee in the zinc naphthenate domestic class product is not required based on the revised risk assessment taking into consideration the density of the ready-to-use domestic class product containing 25% zinc naphthenate. Comments received during the consultation process resulted in some revisions to the required label statements. Appendix I summarizes the comments and provides the PMRA's response. This decision is consistent with the proposed re-evaluation decision stated in PRVD2010-16. To comply with this decision, registrants of products containing copper and zinc naphthenate salts will be informed of the specific requirements affecting their product registration(s).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Copper and zinc naphthenate salts have been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of copper and zinc naphthenate salts. In this decision, the PMRA took into account the Canadian use pattern and issues (for example the federal Toxic Substances Management Policy [TSMPP]).

The USEPA re-evaluated copper and zinc naphthenate salts and published its conclusions in a 2007 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2010-16, *Copper and Zinc Naphthenate Salts*.

What Are Copper and Zinc Naphthenate Salts?

Copper naphthenate is a fungicide and insecticide registered for use as a wood and material preservative to control fungal rot, mildew, wood decay and wood-boring insects (including termites, carpenter ants). Commercial workers can apply products containing copper naphthenate for preservation of joinery wood products in industrial settings using a spraybox, flow coating, or via dipping; for remedial wood treatment of wood surfaces (including shingles, porches, steps and fence posts) using a brush; and for remedial wood treatment of industrial wood products (including in-service utility poles, bridge timbers) using a brush, roller, trowel, pressurized applicator or as an impregnated fabric (pre-manufactured wrap). As a material preservative, commercial workers can apply products containing copper naphthenate to exterior fabric (including tents, awnings, ropes) by dipping. Homeowners can apply ready-to-use products containing copper naphthenate to wood surfaces using a brush.

Zinc naphthenate is a fungicide registered for use as a wood preservative to control fungal rot, mildew and wood decay. There are no commercial products containing zinc naphthenate registered in Canada. Homeowners can apply ready-to-use products containing zinc naphthenate to wood surfaces using a brush.

The use of domestic class products containing copper naphthenate or zinc naphthenate for treatment of fabric is no longer allowed.

Health Considerations

Can Approved Uses of Copper and Zinc Naphthenate Salts Affect Human Health?

Copper and zinc naphthenate salts are unlikely to affect your health when used according to the revised label directions.

People could be exposed to copper and zinc naphthenate salts by working as a mixer/loader/applicator and while coming in contact with treated wood and/or fabric. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Copper and zinc naphthenate salts are unlikely to affect human health provided that further risk-reduction measures are implemented.

Environmental Considerations

What Happens When Copper and Zinc Naphthenate Salts Are Introduced Into the Environment?

Copper and zinc naphthenate salts are unlikely to affect non-target organisms when used according to the revised label directions.

Aquatic organisms could be exposed to copper and zinc naphthenate salts in the environment. Environmental risk is assessed by the risk quotient method - the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a low risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

Copper and zinc naphthenate salts are unlikely to adversely affect the environment if used according to the revised label directions. Improvements to general advisory environmental label statements are required by the PMRA.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of copper and zinc naphthenate salts, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional personal protective equipment (PPE) for workers handling copper naphthenate products as well as individuals handling domestic products
- Limit the use of copper naphthenate-treated fabric to non-residential areas
- Removal of the fabric use from domestic product labels
- Hazard label statements for all end-use products

Environment

- Advisory environmental label statements

Appendix II lists all required label amendments.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix III lists all data requirements.

Other Information

Any person may file a notice of objection³ regarding this decision on copper and zinc naphthenate salts within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

³ As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1.0 Comment on Personal Protective Equipment (PPE) for workers applying copper naphthenate products to in-service utility poles

A detailed description of job activities, as well as PPE worn by workers applying commercial products containing copper naphthenate to in-service utility poles was provided. The registrant indicated that the PPE currently used by workers, even though not specified on the products labels, would sufficiently mitigate potential dermal irritation exposure.

PMRA Response

The PPE consisting of coveralls over a long-sleeved shirt and long pants, chemical resistant footwear, chemical resistant gloves and goggles for all workers during handling, clean up, and repair activities was proposed based on the skin and eye irritation properties of copper naphthenate. In addition, a respirator was proposed for workers applying copper naphthenate products by brush. The PMRA considered the provided rationale, the dermal toxicity profile of copper naphthenate and conditions of use for remedial wood treatment. Consequently, the PMRA determined that the skin irritation potential for workers handling products for remedial wood treatment would be adequately mitigated with the following PPE: a long-sleeved shirt, long pants, elongated chemical resistant gloves, chemical resistant footwear, and protective eyewear. A respirator is required for workers applying copper naphthenate products by brush. Further, commercial labels are required to include warning statements indicating that the product is a skin irritant and workers should avoid contact with the skin. The required label statements are listed in Appendix III.

2.0 Comment on a respirator requirement for workers applying copper naphthenate products by brush for preservation of exterior wood products on an infrequent basis

The Registrant provided a summary of incident reports considered by the USEPA for copper naphthenate products and requested a removal of a respirator requirement for workers using the product on an infrequent basis.

PMRA Response

The PMRA proposed a respirator for workers applying copper naphthenate products by brush for remedial wood treatment based on the inhalation risk of concern. Further, incident reports considered in the USEPA RED indicated that exposure to vapours of products containing copper and zinc naphthenate, alone or in combination, leads to respiratory symptoms. Taking into consideration results of the risk assessment, incident reports, as well as the lack of acute inhalation toxicity studies with the end-use products containing copper naphthenate, the PMRA concluded that a respirator is required for all workers applying the pesticide by brush, including those applying the product on an infrequent basis. The PMRA encourages the registrant to submit acute toxicity studies with their end-use products to the PMRA in order to re-consider a respirator requirement.

Appendix II Revised Label Amendments for Products Containing Copper and Zinc Naphthenate Salts

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect human health and the environment.

- I. For commercial wood and material preservative uses of copper naphthenate, the following statements must be included in the **PRECAUTIONS** section.

Causes skin and eye irritation. Potential skin sensitizer. Do not get in eyes, on skin or on clothing.

For joinery wood preservation in wood treatment facilities.

Workers must wear coveralls over a long-sleeved shirt and long pants, chemical resistant footwear, chemical resistant gloves and goggles during handling, clean up and repair.

For remedial wood treatment.

Workers must wear a long-sleeved shirt, long pants, elongated chemical resistant gloves, chemical resistant footwear and protective eyewear. In addition, a respirator is required for workers applying copper products by brush.

- II. For the commercial material preservative use of copper naphthenate, the following statements must be included in the **DIRECTIONS FOR USE** section.

DO NOT use on any fabric where prolonged skin contact may occur. Treated textiles preserved with copper naphthenate are not to be used in residential settings where bystanders including children may potentially contact treated textiles. This includes around homes, schools, parks, playgrounds, playing fields, public buildings or any other areas where the general public including children could be exposed.

- III. For all commercial wood preservation uses of copper naphthenate, the following statements must be included in the **DIRECTIONS FOR USE** section.

DO NOT apply using an airless sprayer.

DO NOT apply this product to wood that will be used in water.

- IV. The fabric use must be removed from all labels of domestic end-use products containing copper naphthenate or zinc naphthenate.

- V. For domestic products containing copper naphthenate or zinc naphthenate, the following statement must be included in the **PRECAUTIONS** section.

Causes skin and eye irritation. Potential skin sensitizer. Avoid, breathing vapours, contact with skin, eyes and clothing. Wear a long-sleeved shirt, long pants, socks, shoes, and rubber gloves when applying this product.

- VI. For all products containing copper naphthenate or zinc naphthenate, the following statements must be included on a primary panel.

**WARNING EYE AND SKIN IRRITANT
POTENTIAL SKIN SENSITIZER**

- VII. For commercial products containing copper naphthenate, the following statement must be included in the **DIRECTIONS FOR USE** section.

DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans and other waters.

- VIII. For all commercial and domestic products containing copper naphthenate or zinc naphthenate, the following statement must be included in the **DIRECTIONS FOR USE** section.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

- IX. For all commercial and domestic products containing copper naphthenate or zinc naphthenate, the following statements must be included in the **ENVIRONMENTAL HAZARDS** section.

Toxic to aquatic organisms.

Appendix III Additional Data Requirements

The following data are required as a condition of continued registration under section 12 of the PCPA. The registrant(s) of technical copper and zinc naphthenate salts is required to provide these data or an acceptable scientific rationale within the timelines specified in the decision letter that will be send by the PMRA.

DACO 9.5.6 Bioaccumulation study in fish (both copper and zinc naphthenate)